

## REMARKS/ARGUMENTS


Claims 8, 10-14, 17 and 18 have been amended. New claims 47-55 have been added. Claims 1-7, 16, and 21-46 have been withdrawn from consideration. Claims 8-15, 17-20, and 47-55 remain pending in this application upon entry of this amendment.

Claims 8, 10, 11, 13, 14 and 17 have been amended to recite "endothelial estrogen regulated gene-7" instead of the abbreviation "EER-7." Support for this amendment can be found on page 46, lines 22-23 of the specification. Claims 8 and 13 have been amended to recite "scavenger receptor cysteine rich" instead of the abbreviation "SRCR." Support for this amendment can be found on page 4, line 17 of the specification.

Claim 8 has been amended to recite that the isolated nucleic acid encodes an endothelial estrogen regulated gene-7 protein having an amino acid sequence which has at least about 75% sequence similarity with SEQ ID NO: 2. Support for this amendment can be found throughout the specification and in particular on page 8, lines 20-22 and page 18, lines 2-6.

Claim 11 has been amended to depend from new claim 53 rather than claim 10 and to properly recite that the claim is directed to a nucleic acid, rather than a protein. Support for this amendment can be found in original claim 11 and throughout the specification and in particular on page 8, line 23. Claim 12 has been amended to depend from new claim 53 rather than claim 10. Support for this amendment can be found in original claims 5 and 12.

Claim 13 has been amended to recite that the vector comprises a nucleic acid encoding a fragment selected from the group consisting of "a polypeptide having at least about 75% sequence similarity with SEQ ID NO: 2." Support for this amendment can be found throughout

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the specification and in particular on page 8, lines 20-22 and page 18, lines 2-6. This claim has also been amended to fix two typographical errors ("NOs" to replace "Nos" and "domain" to replace "domains").


Claim 18 has been amended to recite specific stringent hybridization conditions (50% formamide, 4XSSC at 42° C) and that the at least 20 consecutive bases of the nucleic acid that hybridize under stringent conditions to SEQ ID NO: 1 "do not hybridize under stringent conditions to nucleic acids encoding other lysyl oxidases." Support for these amendments can be found throughout the specification and in particular on page 20, lines 1-3; page 22, lines 10-13; and page 39, lines 1-7.

Support for new claims 47-50 can be found in original claims 1 and 8 and throughout the specification and in particular on page 18, lines 2-6; page 18, line 28 - page 19, line 1; and page 9 lines 5-8.

Support for new claims 51-54 can be found in original claims 1, 8, and 11 and throughout the specification and in particular on page 8, lines 20-23; page 18, lines 2-6; and page 18, line 28 - page 19, line 1.

Support for new claim 55 can be found in original claims 2, 7 and 13 and throughout the specification and in particular on page 3, lines 14-16; page 30 lines 4-10; and page 41 lines 41-26.

No new matter has been added by way of these amendments.


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**Rejections under 35 U.S.C. § 112, first paragraph- written description and enablement**

Claims 8-10, 13-15 and 17-20 have been rejected for failure to fulfill the written description requirement because the claims are allegedly drawn to a large variable genus of DNA molecules encoding polypeptides with an insufficient limitation on structure. In addition, the Examiner alleges that many structurally and functionally unrelated DNA are encompassed within the scope of the claims, including partial DNA sequences. Finally, the Examiner alleges that the specification fails to describe representative species encompassed by the genus of the claim.

Claims 8-10, 13-15 and 17-20 have also been rejected for failure to fulfill the enablement requirement because the specification allegedly does not enable DNA molecules encoding EER-7 that is different from SEQ ID NO: 2. The Examiner alleges that the claims encompass molecules having very low structural similarity to SEQ ID NO: 2 that exhibit EER-7 protein activity and that it is not routine in the art to screen large numbers of amino acid sequences that result in a similar protein activity.

Applicants respectfully disagree with these rejections. However, in order to advance prosecution of the application, the claims have been amended to require that the claimed nucleic acids encode for EER-7 polypeptides having higher sequence similarity to SEQ ID NO: 2 than previously claimed. For example, claim 8 has been amended to recite that the nucleic acid encodes an endothelial estrogen regulated gene-7 protein that is at least about 75% sequence similarity with SEQ ID NO:2, claim 13 has been amended to recite "a polypeptide having at least about 75% sequence similarity with SEQ ID NO: 2," and claim 18 has been

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amended to recite the high stringency hybridization conditions of 50% formamide, 4XSSC at 42 °C and that the claimed nucleic acid does not hybridize under stringent conditions to other lysyl oxidases. In addition, claim 8 requires that the claimed nucleic acid encodes a protein having lysyl oxidase activity, comprises four copies of a SRCR domain having a sequence greater than 80% similar to a sequence selected from the group consisting of SEQ ID NOs: 3, 4, 5, and 6 and that it further comprises the conserved lysyl oxidase catalytic domain as depicted in SEQ ID NO: 7.

Thus, these claims do not allow for nucleic acids having low sequence similarity to SEQ ID NO: 2. Rather, these claims require that they have a relatively high degree of sequence similarity to SEQ ID NO: 2 (e.g. claim 8: at least about 75%; claim 18: hybridizes under stringent hybridization conditions with SEQ ID NO: 1). It is routine for one skilled in the art to screen for molecules having particular properties. Specifically, it would be routine for one of ordinary skill in the art to screen for polypeptides having lysyl oxidase activity (claim 8) or to screen for nucleic acids that hybridizes under stringent conditions to SEQ ID NO: 1, but that do not hybridize under stringent conditions to nucleic acids encoding other lysyl oxidases (claim 18). In addition, such nucleic acids are well described in the specification (see e.g. page 8, lines 20-23; page 18, lines 2-6; page 18, line 28 - page 19, line 27; and page 23, lines 6-8 of the specification). The specification also provides ample guidance as to what function-conservative variants (i.e. the nucleic acids presently being claimed) are and how to identify them (see page 17 line 19- page 18 line 6 of the specification).

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In view of these arguments and the amendments made to the claims it is believed that these rejections have been obviated. Accordingly, withdrawal of these rejections is respectfully requested.

**Rejections under 35 U.S.C. § 112, second paragraph**


Claims 8-15 and 17-20 have been rejected for indefiniteness. The Examiner alleges that claims 8-15 and 17-20 are indefinite because the terms "EER-7" and "SRCR" are insufficient to convey with clarity that which applicant sees as the invention.

Claims 8, 10, 11, 13, 14 and 17 have been amended to recite "endothelial estrogen regulated gene-7" instead of the abbreviation "EER-7." Claims 8 and 13 have been amended to recite "scavenger receptor cysteine rich" instead of the abbreviation "SRCR." Accordingly, these rejections have been overcome and Applicants respectfully request their withdrawal.

The Examiner has also rejected claims 18-20 as indefinite because the exact hybridization condition is unclear. Independent claim 18 (from which claims 19 and 20 depend) has been amended to recite the specific stringent conditions (i.e. 50% formamide, 4XSSC at 42° C). Thus, the exact hybridization conditions have been made clear. Accordingly, Applicants believe this rejection has been overcome and Applicants respectfully request its withdrawal.

**Rejections under 35 U.S.C. § 102(e)**

Claims 2-10, 13-15 and 17-20 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Publication No. US 2002/0068322 (U.S.S.N. 09/870,110; herein the

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"Meyers application"). The Meyers application was filed on May 29, 2001 and claims priority to provisional application 60/207,650, filed May 26, 2000. Thus, the alleged effective date of the Meyers application is May 26, 2000. However, Applicants do not concede that the Meyers application is entitled to an effective filing date of May 26, 2000.

The Meyers application is understood to be abandoned (see attached USPTO Patent Application Information Retrieval report for this application (printed out on October 7, 2003; Tab 1)). Because the Meyers application has been abandoned, it cannot be considered to claim the same patentable invention as the instant application. Accordingly, a Declaration under 37 C.F.R. § 1.131 can be used to swear behind the Meyers application (see MPEP § 715 "SITUATIONS WHERE 37 CFR 1.131 AFFIDAVITS OR DECLARATIONS CAN BE USED" (B)).

The annexed Declaration of Mark J. Evans, Marshall S. Scicchitano, Ashok R. Bapat, Ramesh A. Bhat, Robert Mastroeni, and Sotirios K. Karathanasis under 37 C.F.R. § 1.131 establishes that the instant invention was conceived and completed at a time prior to May 26, 2000, the alleged effective date of the Meyers reference.

The documents submitted herewith as Exhibit 1 establishes that Mark J. Evans, Marshall S. Scicchitano, Ashok R. Bapat, Ramesh A. Bhat, Robert Mastroeni, and Sotirios K. Karathanasis conceived and completed the instant invention at a date prior to May 26, 2000. Page 1 of Exhibit 1 shows that the inventors had the clone D3E11 in their possession at a time prior to May 26, 2000 and that this clone had a cDNA insert of the expected size for a full length EER-7. Pages 2-3 of Exhibit 1 show that the inventors had obtained the full-length

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nucleotide sequence of EER-7 at a time prior to May 26, 2000. The Declaration under 37 C.F.R § 131 also establishes that the documents submitted herewith as Exhibit 1 was created at a time prior to May 26, 2000.

In view of the Declaration under 37 C.F.R § 131, the anticipation rejection in view of Meyers is moot; Meyers is not available as prior art against the instant application. Accordingly, Applicants respectfully request withdrawal of this rejection.

The annexed Declaration has been executed by only six of the nine named inventors of this application. Applicants' representatives will have the three remaining named inventors execute this Declaration upon verification of their contribution to the pending claims. In the meantime, Applicants respectfully request consideration and entry of the present Declaration under 37 C.F.R. § 1.131.

#### **Supplemental Information Disclosure Statement**

The Supplemental Information Disclosure and its accompanying Form SB/08 submitted concurrently with this amendment discloses U.S. Publication No. 2003/0059919 A1. U.S. Publication No. 2003/0059919 A1 was filed on May 30, 2002 as U.S.S.N. 10/160,501 (the "'501 application"). Applicants respectfully point out to the Examiner that the '501 application is a continuation-in-part application of the Meyers application cited by the Examiner in the present rejection under 35 U.S.C. § 102(e) (U.S.S.N. 09/870,110; U.S. Publication No. US 2002/0068322).

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### Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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